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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,289	03/10/2004	Richard W. Scott	CEPH-2456	3269

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EXAMINER	
HILL, KEVIN KAI	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/797,289	SCOTT ET AL.	
	Examiner	Art Unit	
	Kevin K. Hill, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *77-140* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *77-140* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 77-140, drawn to a method for screening chemical compounds for the ability to decrease *in vivo* levels of Aβ peptide in a gene-targeted rodent containing a human mutation of the presenilin-1 (PS-1) gene and a rodent amyloid precursor protein (APP) gene having a human FAD Swedish mutation of a humanized Aβ nucleotide sequence, classified in class 800, subclass 3.

2. **Should Applicant elect Invention I, a species election is required under 35 USC 121.** Currently, Claims 77-80 of this application is generic to a plurality of disclosed, patentably distinct human mutations of the presenilin-1 (PS-1) gene that prohibit proper examination of this claim. Therefore, election is required under 35 U.S.C. 121 of one mutation from the list consisting of the mutations recited in Claims 137-140 consonant with Applicant's elected invention for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

The Invention I, PS-1 mutation species are unrelated. The mutations do not share a common core structure or function, thus they are patentably distinct. One of ordinary skill in the art could readily consult any genetics, biochemistry or cell biology reference textbook (e.g., Molecular Biology of the Cell, Alberts et al., Garland Publishing) describing the structure, characteristics and biological properties for each of the amino acids and each of the nucleotides in the intron/exon splice donor, the intron/exon splice acceptor site, and the 5' promoter region and would appreciate that based on such reference disclosures alone or in combination with others, that these mutations are distinct and separate. Furthermore, each recited amino acid change represents a distinct genus of codons consisting of distinct nucleotide sequences. Applicants are reminded that nucleic acid sequences encoding different proteins, and the amino acid sequences they encode, are structurally distinct chemical compounds and are unrelated to

one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleic acid and amino acid sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

A reference rendering P264L as anticipated or obvious over the prior art would not necessarily also render a mutation at position –2818 in the 5' promoter as anticipated or obvious over the prior art. Similarly, a finding that an exon 9 splice acceptor site deletion mutation was novel and unobvious over the prior art would not necessarily extend to a finding that M146L was also novel and unobvious over the prior art. Because these inventions are distinct for reasons given above, and because a search of one does not necessarily overlap with that of another, it would be unduly burdensome for the examiner to search and examine all the subject matter being sought in the presently pending claims and thus, restriction for examination purposes as indicated.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed mutation of the human PS-1 gene, even though this requirement is traversed. Failure to elect a mutation of the human PS-1 gene from above consonant with Applicant's elected Invention, may result in a notice of non-responsive amendment.

Should Applicant elect the P264L mutation from list of PS-1 mutations above, a further species election is required under 35 USC 121. Currently, Claims 77-84 of this application are generic to a plurality of disclosed, patentably distinct nucleotide changes at codon 264 of the PS-1 gene that prohibit proper examination of this claim. Therefore, election is required under 35 U.S.C. 121 of one specific nucleotide sequence at codon 264 of the PS-1 gene from the list consisting of the codons recited in Claims 125-126, 128-129, 131-132 and 134-135 consonant with Applicant's elected invention for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

In the instant case, each codon 264 species is independent and distinct. Applicants are reminded that nucleic acid sequences are structurally distinct chemical compounds and are

unrelated to one another, as described above. Furthermore, although each altered codon 264 will result in a new codon for a leucine amino acid rather than a proline amino acid, only one P264L codon alteration will impart a novel and useful AflII restriction site when placed in context with the altered codon 265 recited in claims 127, 130, 133 and 136.

A reference rendering one codon 264 sequence as anticipated or obvious over the prior art would not necessarily also render another codon 264 sequence as anticipated or obvious over the prior art. Because these inventions are distinct for reasons given above, and because a search of one does not necessarily overlap with that of another species, it would be unduly burdensome for the examiner to search and examine all the subject matter being sought in the presently pending claims and thus, restriction for examination purposes as indicated is proper.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election. Failure to elect species consonant with Applicant's elected invention may result in a notice of non-responsive amendment.

Should Applicant traverse on the ground that the species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin K. Hill, Ph.D. whose telephone number is 571-272-8036.

The examiner can normally be reached on Monday through Friday, between 9:00am-6:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DAVE TRONG NGUYEN
SUPERVISORY PATENT EXAMINER